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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/738,317	12/17/2003	Timothy A. Becker	65306-0092	8901

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RADER, FISHMAN & GRAUER PLLC
39533 WOODWARD AVENUE
SUITE 140
BLOOMFIELD HILLS, MI 48304-0610

EXAMINER

BERKO, RETFORD O

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/738,317

Applicant(s)

BECKER ET AL.

Examiner

Retford Berko

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections- 35 USC Sec 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Kipke et al (US 6, 592, 566).

Kipke et al (Patent '566) teach a method for forming endovascular occlusion comprising controlling the injection parameters of purified alginate liquid and a calcium chloride solution into a vascular site (abstract, column 13, lin 10-20 and col 4, lin 35-47).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 1-16 are anticipated by Kipke et al (US 6, 592, 566).

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-32 are rejected as unpatentable under 35 U.S.C. 103(a) over Kipke et al (US 6, 592, 566).

Kipke et al (Patent '566) disclose a method for forming endovascular occlusion comprising controlling the injection parameters of purified alginate liquid and a calcium chloride solution into a vascular site (abstract, column 13, lin 10-20 and col 4, lin 35-47). Kipke discloses a method wherein alginate and calcium chloride solution are simultaneously injected through a catheter into a vessel, the rates for injection determined and controlled in a fashion to enable the two compounds to meet and polymerize at a site (col 4, lin 20-45 and col 12, lin 55-65). According to Kipke et al, the use of purified alginate rather than crude alginate provides the advantage of reduced biological effects (i.e. low immunogenicity or immune response; col 10, lin 5-19).

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One of ordinary skill would have been motivated to use a method for forming endovascular occlusion, such method comprising controlled delivery of purified alginate and calcium chloride to a damaged vessel in the body. One of ordinary skill would expect reasonable level of success in sealing damaged tissue and preventing loss of blood from a tissue site while maintaining low immune reaction and side effects. Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill at the time the invention was made.

Claims 1-32 are rejected as unpatentable under 35 U.S.C. 103(a) over Cochrum et al (US 5, 614, 204) in view of Kipke et al (US 6, 592, 566).

Cochrum et al (Patent '204) disclose angiographic vascular occlusion agents comprising alginates and cations that can be administered in alternative ways (abstract, col 7, lin 25-30, col 9, lin 5-10. According to Cochrum, an advantage in the use of the vascular occlusive agent is reversibility—i.e. the vascular occlusive biopolymer plug may be dissolved by administering non-harmful chelating agents that can dissolve the polymer plug (col 8, lin 1-5) and can be used for selective embolism at sites that ordinarily do not respond to vasopression (col 15, lin 30).

Cochrum et al do not teach controlled and simultaneous administration of vascular occlusive agents comprising alginate and calcium chloride.

Kipke et al (Patent '566) disclose a method for forming endovascular occlusion comprising controlling the injection parameters of purified alginate liquid and a calcium chloride solution into a vascular site (abstract, column 13, lin 10-20 and col 4, lin 35-47). Kipke discloses a method wherein alginate and calcium chloride solution are simultaneously injected through a catheter into a vessel, the rates for injection determined and controlled in a fashion to enable the two compounds to meet and polymerize at a site (col 4, lin 20-45 and col 12, lin 55-65).

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One of ordinary skill would have been motivated to use a method for forming endovascular occlusion, such method comprising controlled delivery of purified alginate and calcium chloride to a damaged vessel in the body. One of ordinary skill would expect to combine the two references cited in order obtain the advantage of administering controlled autologous occlusive agents for forming permanent occlusion and controlling hemorrhage at damaged sited in a manner that provided the physician a quick and convenient way of preparing the agents having no foreign proteins present (i.e. reduced immune reactivity—Patent '204, col 14, lin 55-65 and Patent '566, col 10, lin 5-19). Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill at the time that it was made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Retford Berko** whose telephone number is 571-272-0590. The examiner can normally be reached on M-F from 8.00 am to 5.30 pm

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Thurman K Page**, can be reached on 571-272-0602.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600